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EXAMINER	
SHAPIRO, JEFFERY A	

ART UNIT	PAPER NUMBER
3653	

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/930,599	Applicant(s) FEENEY ET AL.	
	Examiner Jeffrey A. Shapiro	Art Unit 3653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,9,11-15,22,23,31-35,38,39,42 and 69-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,9,11-15,22,23,31-35,38,39,42 and 69-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/29/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/1/03 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 74 recites the limitation "pharmacy benefits manager" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-5, 9, 11-15, 22, 23, 31-35, 38, 39, 42 and 69-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liff et al (US 6,068,156) in view of Thornton

(US 5,628,530). Liff et al discloses the following. **(Note, claims which have been cancelled, have been eliminated.)**

As described in Claims 1, 22, 31, 35 and 44;

1. one or more dispensers (20) configured to controllably release a product in response to a control signal;

2. an admission subsystem (see element (311) and figure 13P) configured to maintain patient information;

3. a prescription subsystem coupled to said one or more dispensers and configured to:

a. receive entry of prescription information;

b. to relate patient information from said admission subsystem to the prescription information to initiate a determination of whether the product is appropriate for the patient;

c. to send a control signal to said one or more dispenser units to release the product;

(See col. 23, lines 12-37, which includes an adjudication step at line 16)

As described in Claims 2, 31, 35, 44 and 46;

4. said determination of whether the medication is appropriate for the patient comprises a pharmacy adjudication (see col. 23, line 16);

As described in Claim 3;

5. said determination of whether the medication is appropriate for the patient comprises a drug utilization review (DUR) (see figure 12, and element (284);

As described in Claims 4, 32, 33, 36, 37 and 3;

6. said prescription subsystem is further configured to manage and control a virtual inventory by tracking ownership and utilization of a plurality of individually owned and co-mingled inventories in said one or more dispensers (note that various inventories are kept track of, including the inventory of several cabinets, and that virtual and actual inventories are functionally equivalent to each other—also note that pharmaceutical companies are also connected to the system, and they necessarily have inventory systems of their own, which necessarily interface with the system of Liff et al);

As described in Claims 5, 34 and 38;

7. access to a medication inventory is further controlled according to ownership of the medication as tracked in said virtual inventory (note that it is necessary for the medication to be matched with the appropriate patient and for medicines in a dispensing cabinet at hospital X to be identified as located at hospital X's cabinet);

As described in Claim 39;

8. said prescription subsystem is configured to manage and control a physical inventory by sending a reorder message to reorder a product

when an inventory level is at a predefined level (note refill function (310), noting that pharmaceuticals are routinely given to patients with the number of refills located on the label, said refill occurring for a particular number of units of that pharmaceutical);

As described in Claim 9;

11. said admission subsystem generates a patient specific drug benefit profile used in prescribing the medication (see elements (336, 337 and figure 13E);

As described in Claims 23 and 51;

12. a sample management subsystem configured to track the distribution of a sample medication to a patient, to associate information gathered from the distribution of the sample medication with said patient information, to initiate a determination of whether the information is appropriate for the patient, and to send a control signal to said one or more dispenser units to release a sample medication (see figures 7B, 7C and 8, noting in figure 8, phase I is directed toward a toxicity levels, phase II is directed towards safety, phase II, toward efficacy and phase IV, to distribution—note also that figure 8 describes administration of drugs during a clinical trial, which can be construed as a functional equivalent of a "sample" distribution);

As described in Claim 11;

13. a patient care subsystem configured to relate said patient information to data collected from the dispensing of an office administered medication and to send a control signal to said one or more dispenser units to release a product (see figure 2, elements (108 and 120);

As described in Claim 12;

14. an over-the-counter subsystem configured to relate said patient information to data collected from the dispensing of an over the counter product, further configured to send a control signal to said one or more dispenser units to release the over-the-counter-product (note that dispensing a prescription or over-the-counter drug is construed to be handled in the same substantially the same fashion, using the same equipment and structure, therefore it is concluded that the system of Liff et al is capable of handling over-the-counter drugs);

As described in Claim 13;

15. the medication is dispensed at a point of care (note that the medication can be dispensed at a hospital or doctor's office, for example, and that any particular place, including a patient's home could conceivably be the location of a cabinet that is secure);

As described in Claim 14;

16. a central server (422) (see also element (573, figure 17, which indicates an internet which implies the presence of a server) connected via a network to said prescription subsystem and configured to receive

and process said determination of whether the medication is appropriate for the patient;

As described in Claims 15 and 42;

17. said central server is coupled to an enterprise resource planning (ERP) system having an accounting module configured to track finances and collection of money, an inventory module configured to manage physical and virtual product inventories, a purchasing module configured to automatically process purchase requests, and a fulfillment module configured to manage product order requests (note that at the very least, these limitations are obvious to one ordinarily skilled in the art to provide, otherwise, the system of Liff et al would not work);

Applicants' amendment filed 6/9/03 includes the following significantly different limitations and changes. Claims which have been cancelled have been eliminated.

As described in Claims 1, 11, 12, 22, 34, and 35;

1. A sample management subsystem coupled to said one or more dispensers and configured to track the distribution of a sample medication to a patient, to initiate a determination of whether the medication is appropriate for the patient, and to send a control signal to said one or

more dispenser units to distribute a sample medication (see above discussions of clinical trials, for example, in figure 8);

2. the word "release" has been replaced by "distribute";

As described in Claims 2, 3, 5, 11 and 14;

3. the word "medication" has been replaced by "product";

As described in Claim 23;

4. the words "or the sample medication" has been added;

As described in Claim 31;

5. a marketing module in communication with said patient information database and said prescription module, the marketing module configured to gather product usage data, to transmit said product usage data, and to receive, in response to the transmission of said product usage data, marketing information for an individual dispensing the product and/or a patient (note that the system of Liff et al stores such information as patient records and that it would, at the very least, be expedient for one ordinarily skilled in the art to use and manipulate such data to determine sales and marketing objectives, the information being, for example, what products were bought by what type of patients and under what circumstances);

As described in Claim 32;

6. a central system comprising a central server in communication with said marketing module, which central system is configured to receive the transmission of said product usage data and to determine appropriate

marketing information to direct to an individual dispensing the product and/or said patient (the marketing information can also be argued to be educational information, since drug marketing information is essentially the same as educational information, discussed above, as taught by Liff et al);

As described in Claim 34;

7. the word "based" has been replaced by "contingent"

As described in Claim 35;

8. an inventory management module configured to control and manage the physical inventory and the virtual inventory of the product, said control and management of said virtual inventory tracking ownership and dispensing of a plurality of individually owned and co-mingled product inventories in said one or more dispensers; (Applicants argue that virtual inventory is different because of the "co-mingling" of inventories, for example, between different doctors in the same practice who use the same dispenser. However, virtual inventories are the same as regular inventories in that they are discrete from each other. In addition, various patients have accounts particular to themselves as do doctors/healthcare providers and pharmacists. See col. 13, lines 7-12, describing that the system monitors patient records and billings and that patient records are accessed on an integrated basis. See also col. 13, lines 28-38, describing that pharmaceuticals are tracked using bar code information and that

accounts receivable, accounting and inventory management modules are integrated. Therefore, at the very least, it would have been obvious to one of ordinary skill in the art to use the information already available-that is the patient records with the doctor and drug dispensed information to account for drugs to a specific doctor in a multi-doctor practice.)

As described in Claim 69;

12. said one or more dispensers configured to controllably distribute a product in response to a control signal by dispensing, releasing or granting access to the product (see prior discussion);

As described in Claim 70;

13. said marketing subsystem is further configured to track and report use of a sample medication and an over-the-counter product and to associate said patient information with said use of the sample medication or the over-the-counter product thereby determining appropriate marketing information to direct to an individual dispensing the sample medication or the over-the-counter product and/or said patient (see prior discussion);

Applicants' amendment filed 12/1/03 includes the following significant new limitations and changes.

Liff does not expressly disclose, but Thornton discloses the following.

As described in Claim 1;

1. a marketing subsystem in communication with said sample management subsystem configured to gather data regarding the distribution of sample medications, to transmit said data, and to receive, in response to the transmission of said data, marketing information for an individual dispensing the sample medication;

(See Thornton, figure 1, which illustrates a marketing system (136) which performs marketing analysis based on information fed through a collection source (134) from the sample management system (elements 10-48 of figure 1), which allow a physician to prescribe a sample medication to a patient. See also Thornton, col. 4, lines 20-22, 29-67, and col. 5, lines 1, 2 and 25-32.)

As described in Claims 31;

2. a sample management module coupled to said one or more dispensers and configured to receive patient information from said patient information database, to send a control signal to said one or more dispenser units to distribute a sample medication, to collect patient specific sample medication usage data, and to provide said sample medication usage data to a user;

(Note that Liff discloses an extensive system with dispensers connected electronically to a patient information system, as described above. Again, Thornton discloses using a marketing subsystem in combination with a

sample subsystem to dispense sample medication to patients through their physician. See also Thornton, col. 2, lines 1-63.)

As described in Claims 32 and 35;

3. a sample management module configured to receive a user request for a sample medication, the sample management subsystem configured to relate said patient information to a requested sample medication, and configured to make the related information available to a third party user; (See Thornton, col. 5, lines 30-32 and lines 64-67, noting that a drug manufacturer and an HMO is considered to be a third party with the physician and the patient being construed as the other two parties. Also note that a "pharmacy computer (130)" is described in col. 5, line 30, which also can be construed as a third party.)

Liff also does not expressly disclose, but Thornton discloses New Claims 71-75, which have been added as follows.

As described in Claim 71;

4. said marketing subsystem further is in communication with said prescription subsystem, the marketing subsystem configured to gather data regarding the distribution of products, to transmit said data, and to receive, in response to the transmission of said data, marketing information for an individual dispensing the product;

(See Thornton, col. 4, lines 20-22, 29-67, and col. 5, lines 1, 2 and 25-32 and also col. 2, lines 1-63.)

As described in Claims 72-75;

5. the third party user is a pharmacy benefits manager;

6. the third party user is a pharmaceutical company representative or a medication supplier;

(See Thornton, col. 5, lines 30-32 and lines 64-67, noting that a drug manufacturer and an HMO is considered to be a third party with the physician and the patient being construed as the other two parties. Also note that a "pharmacy computer (130)" is described in col. 5, line 30, which also can be construed as a third party.)

Note: all other12/1/03 amendments and there relation to the prior art are considered to have been addressed above.

Both Liff and Thornton are considered to be analogous art since Liff discloses a drug dispensing system with physician, patient, pharmacy, hospital and drug manufacturer interfacing and integration with the system. Thornton discloses a sample prescription and marketing system with physician, patient, drug manufacturer, pharmacy and hospital interfacing and integration with the system.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to have added the sample prescription and marketing analysis functions of Thornton's system with the system of Liff.

The suggestion/motivation would have been to track demographics of starter drug samples dispensed to a plurality of patients from a plurality of different dispensing locations." See col. 2, lines 1-8. Note also that Liff discloses accommodating clinical trials of medicines within his system, for example, as illustrated in figure 8 and discussed in col. 13, lines 51-67 and col. 14, lines 1-10. See also Liff, col. 3, lines 5-21, which further mention that Liff's system allows monitoring of drug trials "to determine the drug's effectiveness." One ordinarily skilled in the art would recognize that monitoring of drugs in such clinical trials and sample monitoring are similar functions in that the specific patient and his specific information regarding the sample drug being tried is necessary for both the drug manufacturer and the physician so as to ensure that the desired effects on the patient are realized. Again, note also that Liff's system is intended to be an "all service" system, providing support to patient, physician, HMO, Hospital, pharmacy, drug manufacturer, etc., which all have access, and are interfaced with the system. Finally, as previously discussed, Thornton expressly teaches extracting purely marketing information from such a system as Liff's based on the dispensing of drugs to patients. Such information is construed as demographic information, quantity used, etc, as described in col. 1, lines 31-42 of Thornton. In addition, note that it is recognized that advertising of drugs by the drug industry necessarily involves including specific clinical information, at least on a minimal level,

which would help a doctor to prescribe it to a patient. Liff also implies marketing and advertising since Liff describes his system as interacting with drug manufacturers and pharmacies, for example.

Therefore, it would have been obvious to combine Liff and Thornton in order to obtain the invention as described in 1-5, 9, 11-15, 22, 23, 31-35, 38, 39, 42 and 69-75.

Response to Arguments

5. Applicant's arguments filed 12/1/03 have been fully considered but they are not persuasive. Applicants' limitations presented in the independent claims, reasonably broadly construed, appear to read on the prior art used in the rejections as well as the cited prior art. Applicants' Representative is encouraged to contact the Examiner regarding directions for further amendments.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey A. Shapiro whose telephone number is (703)308-3423. The examiner can normally be reached on Monday-Friday, 9:00 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald P. Walsh can be reached on (703)306-4173. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey A. Shapiro
Examiner
Art Unit 3653

February 9, 2004

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